

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/537,376 | 06/03/2005 | Hidemitsu Kasahara | 050369 | 3565 |
| 23850 75790 657112911 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. 4th Floor WASHINGTON, DC 20005 | | | EXAMINER | |
| | | | ABU ALI, SHUANGYI | |
| | | | ART UNIT | PAPER NUMBER |
| | , | | 1731 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/11/2011 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| Application No. | Applicant(s) | | | |
|------------------|-----------------|--|--|--|
| 10/537,376 | KASAHARA ET AL. | | | |
| Examiner | Art Unit | | | |
| SHUANGYI ABU ALI | 1731 | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

| Period for Reply |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR I.138(a). In or event, however, may a reply be timely filled. - If NO period for reply is appealfied above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failur to reply whinh the set for extending period for reply will, by statute, cause the application to become ABANDONED (38 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any earned partner them adjustment. See 37 CFR 1.704(b). |
| Status |
| 1) Responsive to communication(s) filed on 24 February 2011. |
| 2a) ☐ This action is FINAL . 2b) ☐ This action is non-final. |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. |
| Disposition of Claims |
| 4) Claim(s) 1-20 is/are pending in the application. |
| 4a) Of the above claim(s) <u>5-10 and 14-20</u> is/are withdrawn from consideration. |
| 5) ☐ Claim(s) <u>5-10 and 14-20</u> is/are allowed. |
| 6)⊠ Claim(s) <u>1-4 and 11-13</u> is/are rejected. |
| 7) Claim(s) is/are objected to. |
| 8) Claim(s) are subject to restriction and/or election requirement. |
| Application Papers |
| |
| 9)☐ The specification is objected to by the Examiner. |
| ·· |
| 9) The specification is objected to by the Examiner. |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some col None of: |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some of: 1. Certified copies of the priority documents have been received. |
| 9 The specification is objected to by the Examiner. 10 The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some ON None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some ON None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). |

| Notice of References Cited (PTO-892) | 4) 🗆 |
|-------------------------------------------------------------|------|
| 2) Notice of Draftsperson's Patent Drawing Review (PTO 943) | |
| | 5) |

3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _

| Interview Summary (PTO-413) Paper Ne(s)/I/all Date |
|----------------------------------------------------|
| Notice of Informal Patent Application |

6) Other: __

Art Unit: 1731

DETAILED ACTION

Status of Claims

Claims 1-20 remain for examination, and claims 5-10 and 14-20 are withdrawn.

Claim Rejections - 35 USC § 103

The rejection of claims 1-4 and 11-13 under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 6,663,948 as generally set forth in the previous office action mailed10/29/2010stands.

The text of those sections of title 35 US Code not included in this action can be found in the prior Office Action.

37 CFR 1.132

The declaration under 37 CFR 1.132 filed 02/24/2011 is insufficient to overcome the rejection of claims based upon the unexpected result as set forth in the last Office action because: 1)The data provided are not commensurate in scope with the broadly claimed invention. Claim 1 recites that the compound is heated at a temperature of 100-180 °C with a time duration of 0.1-24 hour. However, applicants only present the heating temperature of 100 °C. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.

2) The prior art disclose teaches the age time can be up to 100 hour and the pH of the reaction condition is 8-10, and the reaction temperature and the

Art Unit: 1731

heating temperature in the range of 20-97 °C. The Examiner respectfully submits that the applicant should conduct the experiment according to the teaching of prior art. For example the prior art disclose that the pH of the reaction is in range of 8-10 and the aging time is 0.1-100 hour and the reaction temperature and heating temperature in the range of 20-97 °C. The applicant only present the reaction temperature of 30 °C and the heating temperature of 97 °C. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.

Response to Arguments

Applicant's arguments filed 02/24/2011 have been fully considered but they are not persuasive.

The applicant argues that the present application does not has a support.

The Examiner respectfully submits that the instant application recites the transitional term "comprising", which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Furthermore the prior art teaches the making of the calcium phosphate, which is a stand alone compound.

The applicant argues that the process of making the calcium phosphate is different. The Examiner respectfully submits that the claims are product-by-process claims. Eventhough product-by-process claims are limited by and defined by the

Art Unit: 1731

process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 77F.2d 695, 698,227 USPQ 964,966 (Fed. Cir. 1985) (citations omitted).

The applicant argues that the declaration present the data demonstrated a criticality commensurate in scope with teh claim limitation. The Examiner respectfully submits that 1)The data provided are not commensurate in scope with the broadly claimed invention. Claim 1 recites that the compound is heated at a temperature of 100-180 °C with a time duration of 0.1-24 hour. However, applicants only present the heating temperature of 100 °C. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. 2) The prior art disclose teaches the age time can be up to 100 hour and the pH of the reaction condition is 8-10 and the reaction temperature in the range of 20-97 ºC.. The Examiner respectfully submits that the applicant should conduct the experiment according to the teaching of prior art. For example the prior art disclose that the pH of the reaction is in range of 8-10 and the aging time is 0.1-100 hour and the reaction temperature and heating temperature in the range of 20-97 °C. The applicant only present the reaction temperature of 30 °C and the heating temperature of 97 °C.. To establish unexpected results over a claimed range.

Art Unit: 1731

applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUANGYI ABU ALI whose telephone number is (571)272-6453. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/537,376 Page 6

Art Unit: 1731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shuangyi Abu-Ali/ Examiner, Art Unit 1731